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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,434	01/07/2002	David Wallach	WALLACH=1D	4966
1444 7590 03/16/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER JIANG, DONG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 03/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	Application No. 10/036,434	Applicant(s) WALLACH ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1, 2, 6 and 10.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
 13. ☒ Other: No amendment to the claims accompanied the response.

Continuation of 11. does NOT place the application in condition for allowance because:

The rejection of claims 1, 2, 6 and 10 under 35 U.S.C. 103(a) as being unpatentable over Seckinger et al. (J. Exp. Med., April 1, 1988, 167(4): 1151-6), in view of Dayer et al. (J. Exp. Med., 1985, 162: 2163-2168) is maintained for the reasons of record set forth in the previous Office Actions.

The declaration of Dr. Rik Derynck under 37 CFR 1.132 filed on 23 February 2007 is acknowledged, and it is insufficient to overcome the above prior art rejection of claims 1, 2, 6 and 10 based upon the Seckinger and Dayer references under 35 U.S.C. 103(a), as set forth in the previous Office actions, because the declaration is largely opinion only, and presents no further factual support. Applicants opinion and argument have been fully considered, but they are not persuasive for the reasons below.

According to MPEP (716.01(c)), in assessing the probative value of an expert opinion, the examiner must consider, among other things, (1) the nature of the fact sought to be established, (2) the strength of any opposing evidence, (3) the interest of the expert in the outcome of the case, and (4) the presence or absence of factual support for the expert's opinion. (1) In the instant case, the nature of the fact sought to be established is whether or not the protein inhibitor of TNF- α of the prior art (the Seckinger reference) is of sufficient purity to allow determination of the N-terminal amino acid sequence. In the declaration, Dr. Derynck points out that Seckinger reported fractionation of a urinary protein mixture using Sephacryl S-200, and a fractionation by Mono P chromatofocusing, and the reference clearly states "whose nature remains to be determined by purification to homogeneity, many bands still being identified in SDS-PAGE of the ... fractions, purification will enable us to ...", indicating that Seckinger was not in possession of a purified protein that could have been even partially sequenced (pages 4-5). Dr. Derynck further indicates, citing literature and experience, that the product of Seckinger was insufficiently pure to allow sequencing (page 11). While Seckinger's product of the fractions might not be sufficiently pure to allow sequencing, the fact is that the mixture was also subject to SDS-PAGE, wherein each band can be sliced out, and a homogeneous protein can be eluted from a single band for sequencing, which is well known in the art. The absence in teaching further sequencing of the protein in the prior art is not probative that the product of Seckinger was insufficiently pure to allow sequencing. (2) Neither the instant specification nor the declaration provides any opposing evidence to support that the product of SDS-PAGE in the Seckinger reference is not sufficiently pure for sequencing. (3) Dr. Derynck does not appear to have an interest in the outcome of the case; (4) finally, Dr. Derynck does not base his opinion on any particular facts directly related to Seckinger's product other than teachings in the art in general, and his own considerable experience in the field, and does not take the SDS-PAGE into consideration. Affidavits or declarations are provided as evidence and must set forth facts, not merely conclusions. In re Pike and Morris, 84 USPQ 235 (CCPA 1949). As such, the declaration of Dr. Derynck under 37 CFR 1.132 is insufficient to overcome the above prior art rejection.

Applicants arguments based on the declaration of Dr. Derynck filed on 23 February 2007 have been fully considered, but they are not persuasive for the reasons above.



LORRAINE SPECTOR
PRIMARY EXAMINER